GMTA/DITTA Workshop on Reliance

- **Scene Setting:** What is reliance and why is it important?
- **Session 1:** Reliance in a premarket setting
- **Session 2**: Reliance in a post market setting
- **Next Steps**

DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

GMTA
Global Medical Technology Alliance
Innovating for a Healthier World

FDA U.S. FOOD & DRUG ADMINISTRATION
IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

Anvisa – Brazil
Post Market Experience

Ana Carolina M. Marino Araujo
Fourth Directorate
Anvisa
March 11, 2024

IMDRF International Medical Device Regulators Forum

Reliance Activities and Anvisa Strategic Priority Plan 2024-2029

- **Anvisa Strategic Priority Plan 2024-2029**

Objective 5: To be recognized as an International Reference Regulatory Authority.

Consolidation of Anvisa leading role in the international scenario, ensuring high standards in all regulatory operations.

Reliance Activities in Inspections

- **Pathways for the grant of GMP Certificates issued by Anvisa**

1. GMP Inspection conducted by Anvisa inspectors with the issuance of an Inspection Report attesting if the company has a Quality Management System and complies with the Good Manufacturing Practices.
2. Based on the information from other Inspection Reports issued by recognized authorities accompanied by a Risk Analysis.
3. Based on MDSAP Inspection Reports and Certificates.

Reference Legislation: RDC 687/2022

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Reliance Activities in Inspections and Resources

CPROD – Coordination for Inspections and Law Enforcement for Medical Devices

- Inspections/audits of companies
- GMP Certification using risk analysis + reliance mechanisms and Anvisa Inspection Reports.
- Investigation of complaints/quality defects and law enforcement actions
- 24

GMP Certification in Numbers

YEAR	GMP Certificates Issued Based on MDSAP Reports by CAUPS (total and % of total)	GMP Certificates Issued Based on Anvisa Inspection + risk matrix by CPROD	Total International GMP Certificates issued
2017	38 (4.7%)	770 (95.3%)	808
2018	107 (19.3%)	447 (80.7%)	554
2019	374 (48.7%)	394 (52.3%)	768
2020	544 (49.1%)	564 (50.9%)	1108
2021	529 (51.4%)	500 (48.6%)	1029
2022	621 (59.7%)	419 (40.3%)	1040
2023	659 (59.1%)	456 (40.9%)	1115

Other Post Market Activities

- **Resources allocated to other activities**
  - Increased number of Post Market Compliance (PMC) Inspections.
    - 85 inspections in the last 4 years * (*pandemic)
    - Previously approx. 4 inspections per year.
  - Increased activities upon the receipt of MDSAP 5-day notice
    - 20 MDSAP 5-day notices – all were assessed, and investigations were conducted:
      - 9 immediate enforcement actions, for example: prohibition of importation;
      - 11 technical complaints confirmed;
      - 01 penalty applied.

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Other Activities

- **Resources allocated to other activities**
  - Investigation of Complaints related to Quality Defects;
    - More than 1600 investigations in the last 4 years* (*pandemic)
  - Launch of Monitoring Programs focused on specific products – laboratory testing.
    - COVID19 diagnosis tests
    - Needles and Syringes
    - Infusion sets

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Monitoring Programs

- **COVID19 diagnosis tests (closed January 2023)**
  - 536 laboratory tests conducted
  - 64.9% approved
  - 35.1% not approved
- **Needles and Syringes (started August 2023)**
  - 21 lab tests conducted
  - 100% approved
- **Infusion sets (started September 2023)**
  - 15 lab tests conducted
  - 66.7 % approved
  - 33.3 % not approved

data obtained on 29 February 2023

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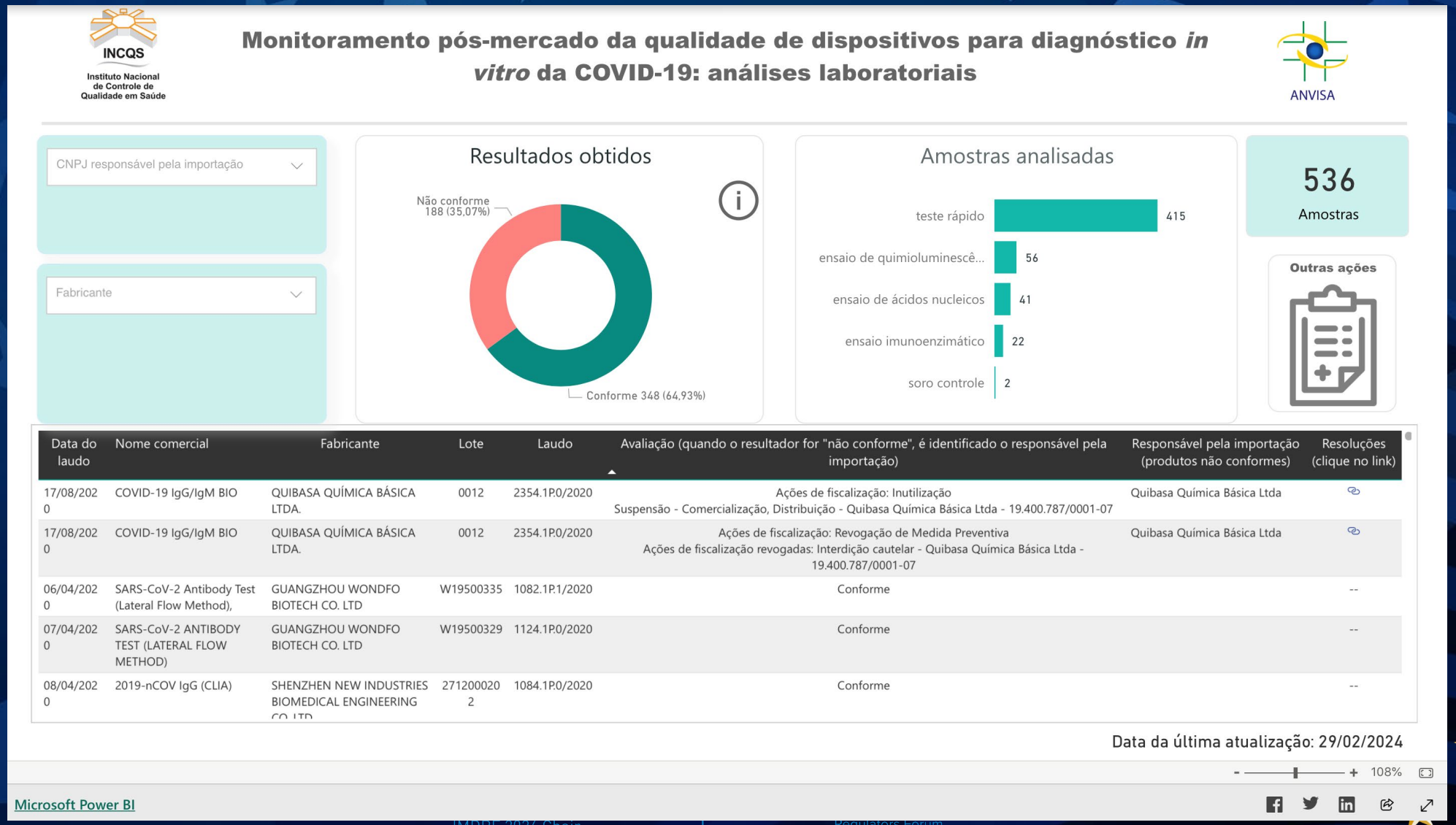
Monitoring Programs



Anvisa Silver Jubilee Celebration

The Agency celebrates 25 years of contributions to public health and to the quality of life of Brazilian citizens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2024